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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,782,919

NOTICE OF FINAL DETERMINATION
AND
REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 5,782,919, which claims the medical device, InFuse® Bone Graft/LT-Cage® Lumbar Tapered Fusion Device, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 348 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extension of U.S. Patent No. 5,984,967 based on the regulatory review period of PMA No. P000058 for the product, InFuse® Bone Graft/LT-Cage® Lumbar Tapered Fusion Device.

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. In the absence of an express election by applicant within one month of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in U.S. Patent No. 5,984,967 will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted. That is, a certificate of extension will be issued in U.S. Patent No. 5,782,919. In the absence of a request for reconsideration and express election of U.S. Patent No. 5,984,967, the Director will issue to the patentee a certificate of extension, under seal, for a period of 348 days in U.S. Patent No. 5,782,919.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of March 28, 2007 (72 Fed. Reg. 14582), would be 990 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,515 \text{ days} - 609 \text{ days}) + 537 \text{ days} \\ &= 990 \text{ days (2.7 years)}\end{aligned}$$

Since the regulatory review period began November 20, 1996, before the patent issued (July 21,

1998), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From November 20, 1996, to and including, July 21, 1998, is 609 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 990 days, would extend the patent from July 17, 2015, to April 6, 2018, which is beyond the 14-year limit (the approval date is July 2, 2002, thus, the 14 year limit is July 2, 2016). The period of extension is thus limited to 348 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, July 21, 2015, to and including, July 2, 2016, or 348 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,782,919
Granted:	July 21, 1998
Original Expiration Date ¹ :	July 21, 2015
Applicant:	Thomas Zdeblick, et al.
Owner of Record:	Warsaw Orthopedic, Inc. ²
Title:	Interbody Fusion Device and Method for Restoration of Normal Spinal Anatomy
Product Trade Name:	InFuse® Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device

¹Subject to the provisions of 35 U.S.C. § 41(b).

²The current assignee according to USPTO assignment records found at Reel/Frame 020309/0212.

Term Extended: 348 days

Expiration Date of Extension: July 2, 2016

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7755
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Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Vill
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Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
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Rockville, MD 20857

RE: InFuse® Bone Graft/LT-
Cage® Lumbar Tapered
Fusion Device
FDA Docket No.: 2003E-0243

Attention: Beverly Friedman